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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,843	02/25/2002	Steven G. Reed	014058-008591US	6245

20350 7590 02/13/2003

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EXAMINER
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SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

*276*

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/084,843

Applicant(s)

REED ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Preliminary Amendment.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 38-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 38-51 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. Applicants' Preliminary Amendment, received 3/12/02, paper#5, is acknowledged. Claims 1-37 have been canceled without prejudice. New claims 38-51 have been added.
2. Claims 38-51 are pending.
3. Claims 38-51 are drawn to a plurality of disclosed patentably distinct nucleotide sequences, i.e., 26-51, 138, 139, 163-183, 201, 240, 242-247, 253-256, 295-298, 309, 316, 318-320, 322, 324, 328, 329, 333, 335, 337, 339, and 341. The listed nucleotide sequences comprise materially different nucleotide sequences as evidenced by separate SEQ ID Numbers. The separate nucleotides bear distinct structural or biochemical properties as evidenced by the separate SEQ ID Numbers. **Therefore, each disclosed patentably distinct nucleotide is considered a separate invention.**

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing which inventions are obvious variants of each other or clearly admit on the record which inventions are obvious variants of each other. If the inventions are deemed obvious variants of each other, then if the examiner finds one of the inventions unpatentable over the prior art, the evidence submitted by applicant or admission of record by applicant may be used in a rejection under 35 U.S.C. §103(a) of the other inventions.

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### **Restriction**

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 38-42, drawn to DNA, vector, and host, classified in class 536, subclass 23.7. Must chose one of SEQ ID NO:26-51, 138, 139, 163-183, 201, 240, 242-247, 253-256, 295-298, 309, 316, 318-320, 322, 324, 328, 329, 333, 335, 337, 339, and 341 as the invention.
  - II. Claims 43-47 and 149, drawn to polypeptide/vaccine encoded by a DNA, classified in class 424, subclass 248.1. Must chose one of SEQ ID NO:26-51, 138, 139, 163-183, 201, 240, 242-247, 253-256, 295-298, 309, 316, 318-320, 322, 324, 328, 329, 333, 335, 337, 339, and 341 as the invention.
  - III. Claim 48, drawn to vaccination method using a polypeptide/vaccine encoded by a DNA, classified in class 424, subclass 9.2. Must chose one of SEQ ID NO:26-51, 138, 139, 163-183, 201, 240, 242-247, 253-256, 295-298, 309, 316, 318-320, 322, 324, 328, 329, 333, 335, 337, 339, and 341 as the invention.
  - IV. Claims 50-51, drawn to detection method and kit using a polypeptide encoded by a DNA, classified in class 424, subclass 9.1. Must chose one of SEQ ID NO:26-51, 138, 139, 163-183, 201, 240, 242-247, 253-256, 295-298, 309, 316, 318-320, 322, 324, 328, 329, 333, 335, 337, 339, and 341 as the invention.

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The inventions are distinct, each from the other because of the following reasons:

Invention I and Inventions II-IV are drawn to structurally and functionally distinct molecules, nucleotides of Invention I and amino acids of Inventions II-IV.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the individual polypeptides of Invention II have separate utility as in immunoassays for detection of anti-mycobacterial antibodies.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the individual polypeptides of Invention II have separate utility as vaccines to induce protective immunity in a host against mycobacterial infection.

Because these inventions are distinct for the reasons given above and the search required for each invention is not coextensive even though there may be overlap, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently


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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

February 12, 2003